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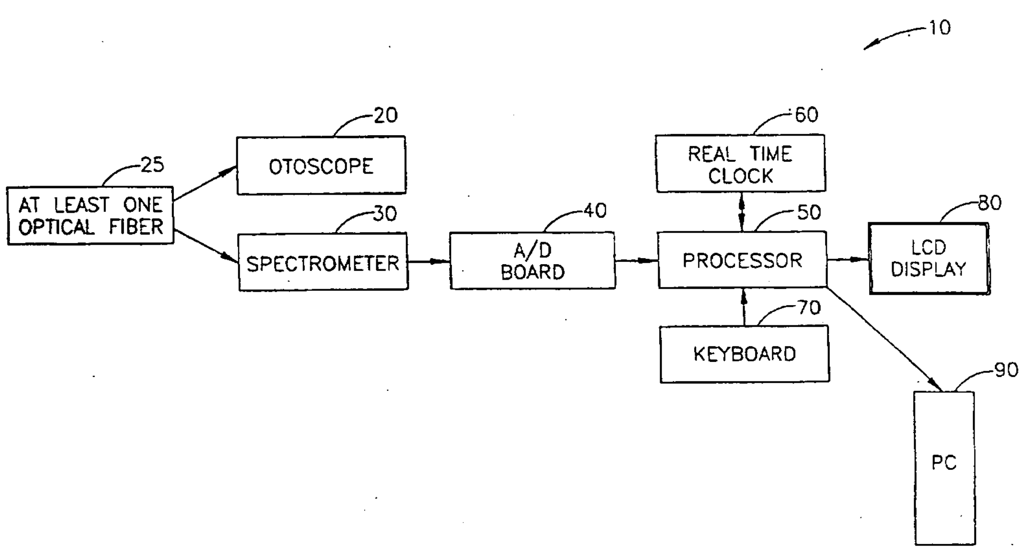
(54) Title: A DIAGNOSTIC SYSTEM FOR THE EAR



(57) Abstract: The present invention concerns to a system for detecting and diagnosing ear related conditions. The invention provides for a device capable of obtaining a spectrum of reflected light from an ear of a subject and a processing unit in connection with said device, which is capable of translating the obtained spectrum of reflected light to one or more output values related to the condition of the ear. The invention further provides a method for detecting and diagnosing ear related conditions comprising the steps of illuminating inside the ear; inserting a device to the ear canal capable of conveying at least one spectrum of reflected light from said ear to a processing unit; and activating said processing unit thereby translating at least one spectrum of reflected light provided at the time of activating to one or more output values related to the condition of the ear.

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A DIAGNOSTIC SYSTEM FOR THE EAR

FIELD OF THE INVENTION

The present invention relates generally to a diagnostic system for ear related conditions. More particularly the invention relates to a system capable of diagnosing ear conditions based on obtaining a spectrum of reflected light from an ear.

BACKGROUND OF THE INVENTION

A wide variety of diseases associated with the human ear have been identified. In children, otitis media is one of the most common pathologies. By itself, otitis media is a significant affliction, which can lead to serious long-term hearing and learning disabilities if not promptly diagnosed and treated with antibiotics. However, overdiagnosis of otitis media is problematic as well, since it causes unnecessary prescription of antibiotics, and excessive hospitalization.

Two major medical conditions are mistakably diagnosed as otitis media: the first one is a healthy ear, in which no medical therapy is of need. The second one is serous otitis media which is an allergic reaction or which is caused by a virus. Not only does serous otitis media cause the prescription of an overdose of antibiotics, it also requires a different treatment.

These ear pathologies are generally diagnosed using common diagnostic techniques, such as tympanometry or visual otoscopy.

Relating to otoscopy, it is quite clear that physicians should not rely solely on the otoscope to diagnose the medical condition of the ear. Otoscopy is largely subjective because it is a visual examination. Therefore, it usually results in overdiagnosis of otitis media.

SUMMARY OF THE INVENTION

One embodiment of the present invention is related to a system for detecting and diagnosing ear related conditions comprising a device capable of obtaining a spectrum of reflected light from an ear of a subject and a processing unit in connection with said device, which is capable of translating the obtained spectrum of reflected light to one or more output values related to the condition of the ear.

In one embodiment of the invention the system of the invention may be in the form of a single hand – held unit.

The system of the invention is able to determine whether the ear is healthy, or is infected with either otitis media, or serous otitis media and to further indicate the statistical confidence of its determination.

Further, in another embodiment of the invention the system is able to determine the redness degree of the tympanic membrane compared to a healthy ear.

A further embodiment of the present invention, the system is able to determine the effusion degree in the middle ear compare to a healthy ear.

According to a further embodiment of the present invention there is provided a method for detecting and diagnosing ear related conditions comprising the steps of illuminating inside the ear; inserting a device to the ear canal capable of conveying at least one spectrum of reflected light from said ear to a processing unit; and activating said processing unit thereby translating at least one spectrum of reflected light provided at the time of activating to one or more output values related to the condition of the ear.

1,2,4 and 5. The processing unit comprises a spectral analytical instrument for receiving the reflected spectrum; and a microprocessor or a computer chip for processing the analyzed spectrum so as to obtain information regarding the medical condition of the ear.

While in one embodiment of the system and method of the present invention otitis media may be diagnosed, in alternate embodiments other diseases may be diagnosed.

In one embodiment of the present invention the spectral analytical instrument includes one or more filters which transmit specific wavelengths.

In another embodiment of the present invention as exemplified in Figs. 1 and 3-5, the spectral analytical instrument includes a spectrometer, which, in a specific embodiment of the present invention, is sensitive to visible and near infra red radiation (e.g., wavelength of 400nm to 1200nm). Thus, the principles of The Near Infrared Spectroscopy, which are well known in the prior art as been described in K.H. Norris, J. Near Infrared Spectrosc. 4, 31-37 (1996) and in Handbook of Near Infrared Analysis, Donald A. Burns, Emil W. Ciuczak, (1992), P. 1-18, may be applicable herein.

The present invention will be more completely understood through the following detailed description, which should be read in conjunction with the attached drawings. All references cited herein are hereby incorporated by reference.

Referring now to Fig. 1 in which a block diagram of a system 10 is shown in accordance with one embodiment of the present invention. The system 10 includes a device 20 for inserting into an ear, illuminating the ear, for example its tympanic membrane and obtaining reflected light. Device 20 may

means for illuminating the ear dram is a halogen lamp, wherein the luminescence reflected on the ear dram through the inner tip housing 24. Other illuminating means may be used. In one embodiment at least one optical fiber 11 is extended from the inner tip housing 24, through the elongated housing 22 and is fanned out in the proximal end 21. An electo-optical cable 25 is further connected to spectrometer 30 (Fig. 1). On the exterior of the elongated housing 22 may be provided a freeze button 27, which is connected to the processor 50 (Fig.1), such that when the freeze button is pressed, it activates processor 50. In one embodiment of the present invention when the freeze button 27 is pressed, processor 50 obtains and analyzes one spectrum of reflected light provided at the time of activating. In another embodiment of the present invention when the freeze button 27 is pressed, processor 50 (Fig.1) obtains and analyzes more than one spectrum of reflected light provided at the time of activating and at a followed period of time as been predefined. A device such as a freeze button need not be used.

In one embodiment, a white patch standard reference spectrum may be acquired, before the device is used to test an ear. When not in use, the device is placed on a stand, with the optic fiber facing a standard white patch. In order to remove the device from the stand, the freeze button 27 may be pressed and by doing so, a sample of the spectrum of the white patch is acquired. This spectrum is then used as a reference spectrum for calculating the relative reflectance spectrum of the ear. Other methods may be used to calibrate the device.

Referring now to Fig. 3 in which a processing unit 100 is shown. In front of processing unit 100 there is an LCD panel indicated as 80 and a

of each soft key. When the system is powered on, it displays the current time on the upper line provided by clock 60. The soft keys are start and set. Pressing the start key will put the system in measurement state where it waits for the doctor to press the freeze button 27 on the device to make the actual measurement. When the freeze button is pressed the data is saved and processed. After processing is complete, the result is displayed on the top line. LCD 80 displays the result, which may be either "normal" or "serous otitis media" or "otitis media" or "undiagnosable". The result is provided with the statistical significance of the classification decision. In other embodiments, other displays and data entry systems may be used, and other diagnosis may be produced.

When result is displayed the doctor has the option to save the data by pressing the soft key. When saving the data the doctor is asked to enter the patient ID on the numeric keyboard 70, and press the left soft key for the ear side.

In one embodiment the data may be saved at the first free location found inside processor 50. Data is saved in files, each file includes a patient ID, ear side, current date and time provided by clock 60 and actual spectrometer data (two bytes per point). If more then one file was saved for the same patient on the same ear, a serial number will be appended to the name.

In one embodiment of the present invention the processing unit 100 is miniaturized to be used as a single hand held unit 100a, built in with an otoscope as shown in Fig. 4.

2) Model evaluation

3) Comparison of specific digital values of specific wavelength to corresponding reference values.

In other embodiments other processes may take place.

Smoothing and derivative

In one embodiment, the operation performed on the at least one digital value is differentiation (first or higher order derivative) with smoothing in a local window (n points). The algorithm for smoothing and calculating the derivative can be simplified to a linear combination as follows:

$$D_i = \sum_{j=-n/2}^{j=n/2} \mathrm{Sigma}(C_j * S_{i-j})$$

Wherein:

D_i – Smoothed derivative value at point i;

i – Index of point;

C_j – Smoothing and differentiation coefficients;

S – Value of spectrum point;

n – window width for smoothing and differentiation operation.

The coefficients C_j are calculated off-line using smoothing and differentiation algorithms and the calculated values are input to the processor 50 by a qualified technician. There may be a different set of coefficients for the first points and for the last points in the vector. The above equation is evaluated for every digital value. The result is a new vector of the derivative. Calculations

Linear discriminant models can be formulated as a linear combination of the derivative vector with a set of multiplying coefficients. The coefficients are calculated using statistical optimization techniques like Regression Analysis. The confidence level of the class determination of each vector is also computed. Therefore, the output of the model consists of two numbers: one represents the class that the ear under evaluation belongs to, and the second represents the statistical significance of the classification decision.

In a case where the statistical significance of the classification decision is low, the output to the LCD display 80 is 'undiagnosed'.

Different classification models can be implemented to mathematically manipulate the processed vector D_i. For example, neural network classifiers, non parametric classifiers (e.g. K Nearset Neighbors) etc. All models yield the same output: classification to (1) normal, (2) serous otitis media or (3) otitis media and statistical significance (confidence level) at which the class was determined.

<u>Comparison of specific digital values of specific wavelength to corresponding reference values</u>.

In addition to the output regarding the classification and the statistical significance, specific information can further be provided regarding the degree of redness of the tympanic membrane and the degree of effusion (fluid) in the middle ear. This information can be provided, in one embodiment of the present invention, when at least one digital value further includes values of the reflectance at wavelengths of, for example 650-700nm and 962nm. As it is well known in the art 962 nm is the wavelength of reflactance of water, and 650-700nm is the range of wavelengths of reflection of the red color in the white

included 258 patients, out of which 511 samples were usable and were analyzed.

Data analysis was performed in two stages: (1) A statistical model was built from part of the data set (training/calibration)and (2) The constructed model was used to predict the rest of the samples of the data (testing/validation)

In order to obtain robust results, the above procedure was performed several times and the average performance is reported in what follows (cross validation of the model by venetian blinds).

The performance of the models was evaluated by four parameters:

1. Percentage of AOM cases (out of all AOM cases) that were correctly predicted.
2. Percentage of AOM cases (out of all AOM cases) that were not correctly predicted (false negative)
3. Percentage of NORMAL cases (out of all NORMAL cases) that were erroneously predicted as AOM (false positive (N)).
4. Percentage of SOM cases (out of all SOM cases) that were erroneously predicted as AOM (false positive (S)).

The analysis was performed on the whole data base, as well as on a subset of the data base that included only patients under 12 years old.

Table 1 summarizes the results by depicting the performance factors, as defined above:

Claims

1. A system for detecting and diagnosing ear related conditions comprising:

   a device capable of obtaining a spectrum of reflected light from an ear of a subject; and

   a processing unit in connection with said device which is capable of translating the obtained spectrum of reflected light to one or more output values related to the condition of the ear.

2. The system of claim 1 wherein the processing unit translates the obtained spectrum by converting the obtained spectrum to at least one digital value and by further comparing between the digital value and at least one reference value.

3. The system of claim 1, wherein said device capable of obtaining a spectrum of reflected light from an ear comprises:

   a lamp; and

   a light conveyor conveying reflected light from said ear to said processing unit.

4. The system of claim 3, wherein said lamp includes a halogen lamp.

5. The system of claim 3, wherein said light conveyor includes at least one optical fiber.

6. The system of claim 2, wherein said processing unit comprises a spectral analytical instrument, which receives said spectrum of reflected light and produces an analog signal.

18. The system of claim 2, wherein said at least one reference value is at least one digital value resulting from diagnosing the other ear of said subject with said system.

19. The system of claim 2, wherein said at least one reference value is at least one digital value resulting from a diagnosis of a healthy ear with said system.

20. The system of claim 2, wherein said at least one reference value is a statistical range values resulting from healthy ears.

21. The system of claim 2, wherein said at least one reference value is a statistical range values resulting from ears with otitis media.

22. The system of claim 2, wherein said at least one reference value is a statistical range values resulting from ears with serous otitis media.

23. The system of claim 2, wherein at least one digital value includes at least one digital value of an reflactance at wavelength of approximately 650-700nm, and wherein the processing unit further compares said value to a statistical reflactance at wavelength of approximately 650-700nm of a healthy ear thereby determining the redness degree of the tympanic membrane of said ear.

24. The system of claim 2, wherein at least one digital value includes a digital value of an reflactance of wavelength of approximately 962 nm, and wherein the processing unit further compares said value to a statistical reflactance at wavelength of approximately 962 nm of a healthy ear thereby determining the effusion degree in the middle ear.

a spectrometer that receives a reflect light from an ear and produces an electrical signal;

an electro-optical cable that delivers said reflected light from an ear to an entrance slit of said spectrometer;

an A/D converter that receives the output of said spectrometer in a form of an electrical signal and converts it to at least one digital value;

a processor that receives said digital value, analyzes the information and saves it;

a clock;

an alphanumeric display connected to said processor and displays a result after processing is completed; and

a keyboard connected to said processor that enables the entrance of data.

35. The device of claim 34, wherein the processing unit is in connection with an otoscope, and the combined components are capable of translating an obtained spectrum of reflected light to one or more output values related to the condition of the ear.

36. The device of claim 34, wherein said alphanumeric display is a LCD.

37. The device of claim 34, wherein said results that are displayed after processing is completed is either "normal" or serous otitis media" or "otitis media" or "undiagnosable".

38. A method for detecting and diagnosing ear related conditions comprising the steps of:

illuminating inside an ear;

converting said spectrum to at least one digital value, and by further comparing between said digital value and at least one reference value to produce at least one output value related to the condition of the ear.

43. A system for detecting and diagnosing ear related conditions comprising:

a device capable of obtaining a spectrum of reflected light from an ear of a subject; and

a processing unit in connection with said device that comprises a spectral analytical instrument, that receives said spectrum of reflected light and produces an analog signal translated to one or more output values related to the condition of the ear.

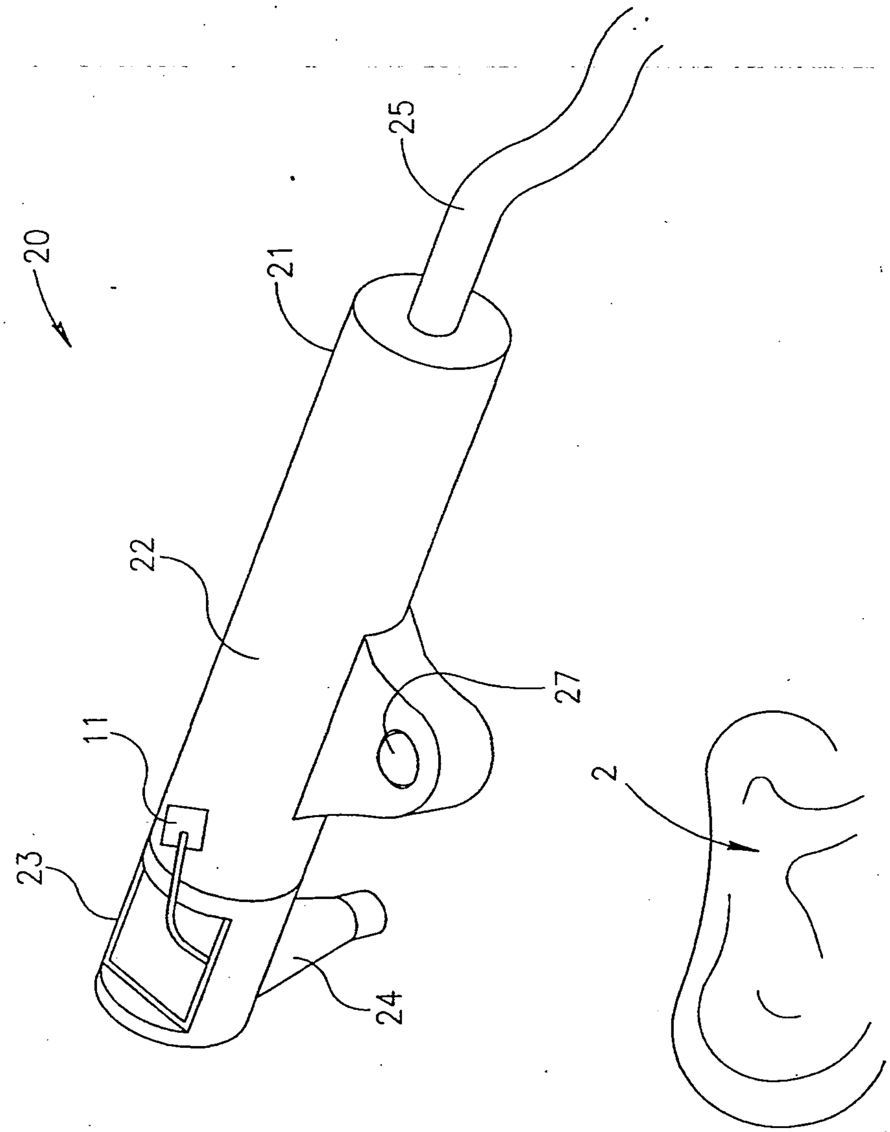

FIG.2

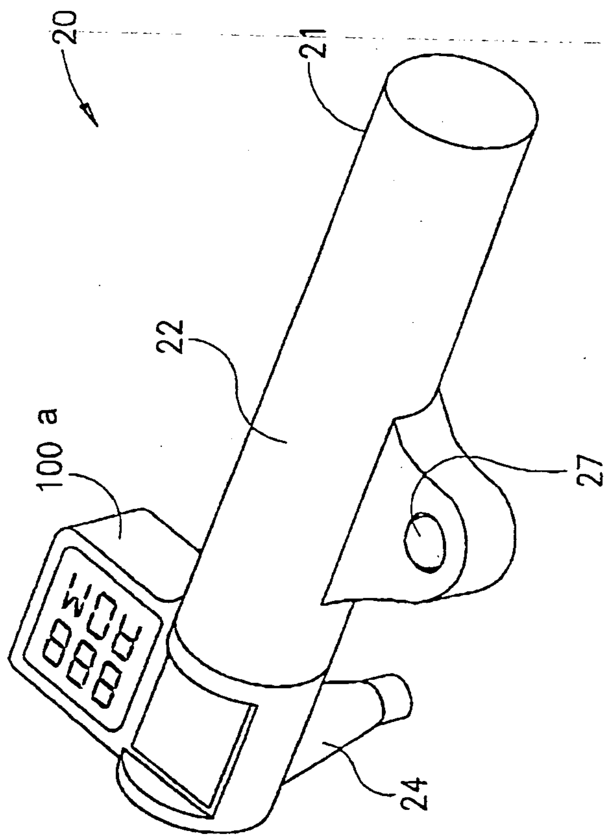

FIG.4